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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/993,322 | 11/06/2001 | Derry Roopenian | JL-2010 | 5668 |

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| EXAMINER | |
|---|---|
| LI, QIAN JANICE | |
| **ART UNIT** | **PAPER NUMBER** |
| 1632 | |

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/993,322 | ROOPENIAN, DERRY | |
| | Examiner | Art Unit | |
| | Q. Janice Li | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 April 2004* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-86* is/are pending in the application.

4a) Of the above claim(s) *1-29,31-46 and 65-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30,47-64 and 81-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) ____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4/16/04
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

The amendment, and response filed 4/16/04 have been entered. Claims 30, 47, 48, 52, 53, 58, 59, 62, 63, 81-84 have been amended. Claims 30, 47-64, and 81-86 are under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated.

### *Specification*

The newly submitted revised abstract contains the word, "described". Applicant is reminded of the proper language and format for an abstract of the disclosure.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Appropriate correction is required.

### *Claim Rejections*

Claims 47, 52, 57, 61, 83-86 are objected to because of the claim recitation, "transgenic knockout mouse". The insertion of a transgene would intrinsically disrupt an endogenous gene. Amending the phrase to "transgenic mouse" would obviate this objection.

Applicant is advised that should claims 52, 57, and 61 be found allowable, claims 84-86 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30, 47-64, and 81-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 is vague and indefinite because the method steps involve using at least two transgenic mice, i.e. one who received the candidate inhibitor and one who does not receive the candidate inhibitor, yet steps a) through c) only provide one transgenic mouse.

Claims are vague and indefinite because of the claim recitation "a muFcRn-/-, +huFcRn transgenic mouse" or "a muFcRn-/- transgenic mouse". Although the specification provides definitions for the recited term, it is noted that the provision of 35 U.S.C. § 112, second paragraph requires claims must, under modern claim practice, stand alone to define invention. The following recitation exemplifies the necessary amendment to claims when the above terms first appear in the claim:

> [providing] A transgenic mouse whose genome comprises a homozygous disruption in its endogenous FcRn gene, and whose genome further comprises a DNA

sequence encoding a human FcRn operably linked to a regulatory sequence, wherein said homozygous disruption prevents the expression of a functional endogenous FcRn protein, and wherein the mouse expresses a functional human FcRn protein (a muFcRn-/-, +huFcRn mouse).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47-56, 83, 84 stand rejected and claims 47-60, and 81-85 are newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Amended claims 47, 52, 83, 84 are now directed to administering a formulation via non-intravenous routes, and measuring the formulation in the bloodstream. However, the specification fails to teach whether the non-intravenous routes such as oral, aerosol, nasal administration would deliver sufficient amount of the formulation to the bloodstream so that a measurable difference could be seen. The only means of delivery provided in the specification is the intraperitoneal route, which is known to reach the circulation reasonably well, whereas a protein formulation may be destroyed before it reaches the bloodstream when administered via oral route. Moreover, non-intravenous administration encompasses the intracardiac administration, which would deliver the formulation directly to the bloodstream, and which does not appear to be desired as now claimed.

Claims 50 and 55 depend from claims 47 and 52, which have been amended to recite "a method to identify a candidate agent for FcRn-mediated drug delivery into the bloodstream". However, the depended claims 50 and 55 recite the candidate agent is transported to various cells via the FcRn, thus it appears that the drug is delivered to those cells rather than bloodstream, and thus the step appears to be inconsistent with the preamble of the claims.

Claims 47-56, and 81-84 are drawn to a method for identifying a candidate agent that facilitates FcRn-mediated drug delivery, the method comprises a step of assaying and comparing the levels of the formulation containing a candidate agent in the bloodstream of the muFcRn-/-, +huFcRn mouse vs. the muFcRn-/- mouse, with a substantially higher amount of the formulation in the bloodstream of the muFcRn-/-, +huFcRn mouse being an indication that the candidate agent facilitates FcRn-mediated drug delivery. However, because the FcRn-/- mouse lacks FcRn protein, and thus is incapable of retaining IgG in its bloodstream such as indicated in figure 7 of the specification, it is expected that the levels of the formulation would be substantially lower in the muFcRn-/- mouse as compared to the muFcRn-/-, +huFcRn mouse regardless whether the candidate agent facilitates the FcRn-mediated drug delivery. Accordingly, in the absence of evidence to the contrary, the methods as claimed do not appear to be enabled to identify the desired candidate agent.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JANICE LI
PATENT EXAMINER

Q. Janice Li
Patent Examiner
Art Unit 1632

QL
July 2, 2004